REMARKS

Applicants thank the Office for the attention accorded the present Application in the November 7, 2007, Office Action. In that Action, the claim of priority to provisional application no. 60/227,249 was regarded as ineffective, Claims 17-20 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement, Claim 15 was rejected under 35 USC §102(b) as being anticipated by Krumholz et al., Annals of Internal Medicine, 1996, Vol. 124, No. 3, Claims 16-20 were rejected under 35 USC §103(a) as being unpatentable over Krumholz et al. as applied to Claim 15 and further in view of Byrne et al. (US 5,156,849). Applicants respectfully traverse.

Applicants have amended the statement of related applications at the beginning of the specification to correct the provisional application serial number that contained a typographical error. No new matter has been added.

The Office states that upon inspection of provisional application number 60/222,249 filed August 1, 2000, there is no recitation of prevention of secondary cardiovascular prevention. Applicants respectfully traverse.

In both the provisional application and the present application, there is support for secondary cardiovascular prevention. In the last paragraph of page 1 and the first paragraph of page 2 of the provisional application and paragraph [0003] of the present application, there are disclosed "primary prevention" trials and "secondary" trials. The primary prevention trials included 22,071 apparently healthy men aged 40 to 84 years and showed a 44% reduction in nonfatal heart attacks. Consequently, aspirin is

recommended for primary prevention of myocardial infarction.

Secondary prevention was disclosed where meta-analysis of randomized secondary trials (which involved people with a history of occlusive vascular disease) demonstrated that aspirin reduced the ***subsequent*** incidence of heart attack, stroke and death by about 25%. Additionally on page 3, third sentence of first paragraph of the provisional application and paragraph [0006] of the present application, it is further stated that large studies indicate that tens of thousands of lives could be saved each year if more people were utilizing a beta-blocker ***after*** having a heart attack. The words "utilizing after a heart attack" and "secondary prevention of heart attacks" are understood by those of ordinary skill in the art as being synonomous.

Applicants respectfully state that there is sufficient basis and recitation in both the provisional application and the present application that supports secondary prevention (i.e., use after a heart attack).

35 USC §112, first paragraph rejection:

The Office has rejected Claims 17-20 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Office states that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office states that there is no mention of exclusion of the hypertensive patients found in the instant specification. Applicants respectfully traverse.

Applicants assert that the exclusion of hypertensive patients represents a limitation on the full scope of individuals for whom the method was previously claimed. Individuals with heart attacks are frequently hypertensive. As previously disclosed above, Applicants' disclosure provides support to a broad category of "patients with heart attacks" that includes both patients with hypertension and patients without hypertension. (See Applicant's disclosure in Paragraphs [0003], [0004], [0006], [0007], [0008], [0012], and [0015]). In fact, Table 2 of Krumholz et al. cited by the Office reports that 50% (2750/5490) of individuals with heart attacks in their sample have hypertension. Consequently, about half of individuals with heart attacks are not hypertensive. The category of "individuals with heart attacks" is therefore understood by those of ordinary skill in the art to connote a substantial cohort of individuals with hypertension as well as a substantial cohort of individuals without hypertension.

In *Ex parte Parks*, the Board stated that adequate description under the first paragraph of §112 does not require literal support for the claimed invention. The Board further stated that it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that the applicant had possession of the concept of what is claimed. *Ex parte Parks*, 30 USPQ2d 1234 (B.P.A.I. 1994). Applicants' broad description of individuals with heart attacks is understood by those of ordinary skill in the art that Applicants had possession of the concept, i.e. Applicants' method of secondary cardiovascular prevention, of treating all individuals, which include individuals with and without hypertension. Krumholz et al. cited by the Office provides evidence of the knowledge of those of ordinary skill in the art.

Claims 17-20 are drawn to a sub-category and, thus, are narrower in scope relative to the disclosed concept. Applicants know of no citable caselaw from either the Board or the Federal Circuit where claims of a narrower scope than that described in the written description are in violation of the written description requirement, especially when the genus (i.e. the category of individuals with heart attacks) includes the species (i.e. the subcategories of individuals with heart attacks that are hypertensive and those that are not hypertensive). Claims 17-20 limit the treatment methods to the smaller sub-category of individuals without hypertension to the exclusion of those individuals with hypertension in the main category.

In light of the arguments presented, Applicants respectfully submit that the 35 USC §112, first paragraph, rejection of Claims 17-20 has been successfully. Allowance is therefore requested.

35 USC §102(b) rejections:

The Office has rejected Claim 15 under 35 USC §102(b) as being anticipated by Krumholz et al., Annals of Internal Medicine, 1996, vol. 124, No. 3. The Office states that, since no details are given regarding the "single dosage unit," the language of the claim reads on two single agents, an aspirin tablet and a beta-blocker tablet in a container to be administered together such as a dosage cup. Applicants respectfully traverse.

Applicants refer the Office to Paragraph [0009] of the present application that describes "... incorporating the desired beta-adrenergic blocking agents and atagonists

of platelet function into a single dosage unit." Also, the present application describes these agents as being "incorporated together into a single formulation" (See Paragraph [0028]). Further, Paragraph [0020] of the present application specifies that "...formulations may be in tablet, capsule, caplet, syrup, liquid, or other dosage forms..." Yet still further, the ordinary meaning of the term "incorporate" means

> 4. to form or combine into one body or uniform substance, as ingredients.
> *Dictionary.com Unabridged (v 1.1).* Random House, Inc. 04 Mar. 2008.

Applicants maintain that "incorporating agents together" into "single dosage units", as a "single formulation" that may be in "tablet or capsule form," is clearly distinct from placing two separate medications together in a medication dispenser such as a dosage cup as suggested by the Examiner. Applicants note that Krumholz et al. contain no comparative teaching to ***incorporate*** aspirin and other agents together into a single dosage unit as a tablet or capsule.

In light of the arguments presented, Applicants respectfully submit that the 35 USC §102(b) rejection of Claim 15 has been successfully traversed. Allowance is therefore requested.

35 USC §103(a) rejection:

The Office has rejected Claims 16-20 under 35 USC §103(a) as being unpatentable over Krumholz et al. as applied to Claim 15 and further in view of Byrne et al. The Office states that Krumholz et al. teach that patients treated with aspirin during

hospitalization and patients prescribed beta-blockers at discharge were more likely to be treated with aspirin at discharge following acute myocardial infarction. The Office further states that the prescribed use of aspirin at discharge correlates with several indicators of better health status. The Office concludes that, motivated by these teachings of Krumholz et al. and in view of Byrne et al. who disclose a combination of a beta-adrenergic blocking agent and aspirin in a single dosage unit, it would be obvious to employ aspirin and beta-adrenergic blocking agent encompassed in a single dosage formulation to prevent secondary heart attacks.

Applicants point out that Byrne teaches beta-blockers as an antihypertensive agent but contains no teaching or suggestion for secondary prevention of a heart attack. Likewise, Krumholz et al. also contains no teaching of beta-blockers for secondary prevention of heart attacks. Applicants maintain, that contrary to the Office's assertion, the combined references of Krumholz et al. and Byrne et al. do not make it obvious to employ aspirin and beta-adrenergic blocking agent in a single dosage formulation to prevent secondary heart attacks, since secondary prevention of heart attacks is not considered in either reference at all.

In further contradiction to the Office's statements regarding Krumholz et al., Applicants direct the Office's attention to Table 2 of the study of Krumholz et al. Twenty-four percent (24%) of patients (1337/5490) who might have benefited from aspirin at hospital discharge did not receive this treatment, despite that it is acknowledged to prevent future heart attacks. More disappointing yet, sixty-six percent (66%) of patients (3614/5490) who might have benefited from beta-blockers at hospital discharge, a

treatment also acknowledged to prevent recurrence of a heart attack and mortality, did not receive this treatment. **The data is not trivial.** In fact, the report of Krumholz et al. corroborates and supports Applicants' arguments and Applicants' disclosure of the need for means and methods to effect improvement in the secondary prevention of heart attacks.

In light of the arguments presented, Applicants respectfully submit that the 35 USC §103(a) rejection of Claims 16-20 has been successfully traversed. Allowance is therefore requested.

Applicants believe that all of the pending claims should now be in condition for allowance. Early and favorable action is respectfully requested.

The Examiner is invited to telephone the undersigned, Applicant's attorney of record, to facilitate advancement of the present application.

Respectfully submitted,

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Robert R. Deleault, Reg. No. 39,165
Attorney for Applicants
41 Brook Street
Manchester, NH 03104
Tel. (603) 668-1971
Fax (603) 622-1445

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Robert R Deleault